PSJ14 Janssen Opp Exh 20 – JAN-MS-00615319

DURAGESIC®

2001 Business Plan

August 2000

Agenda

- Market Overview
- Lessons Learned
- SWOT
- Key Issues
- 2001 Business Objectives
- Strategies/Key Tactics
- Medical Affairs Update
- Market Research Overview
- Business Imperatives
- Forecast & PME Requirements
- Summary

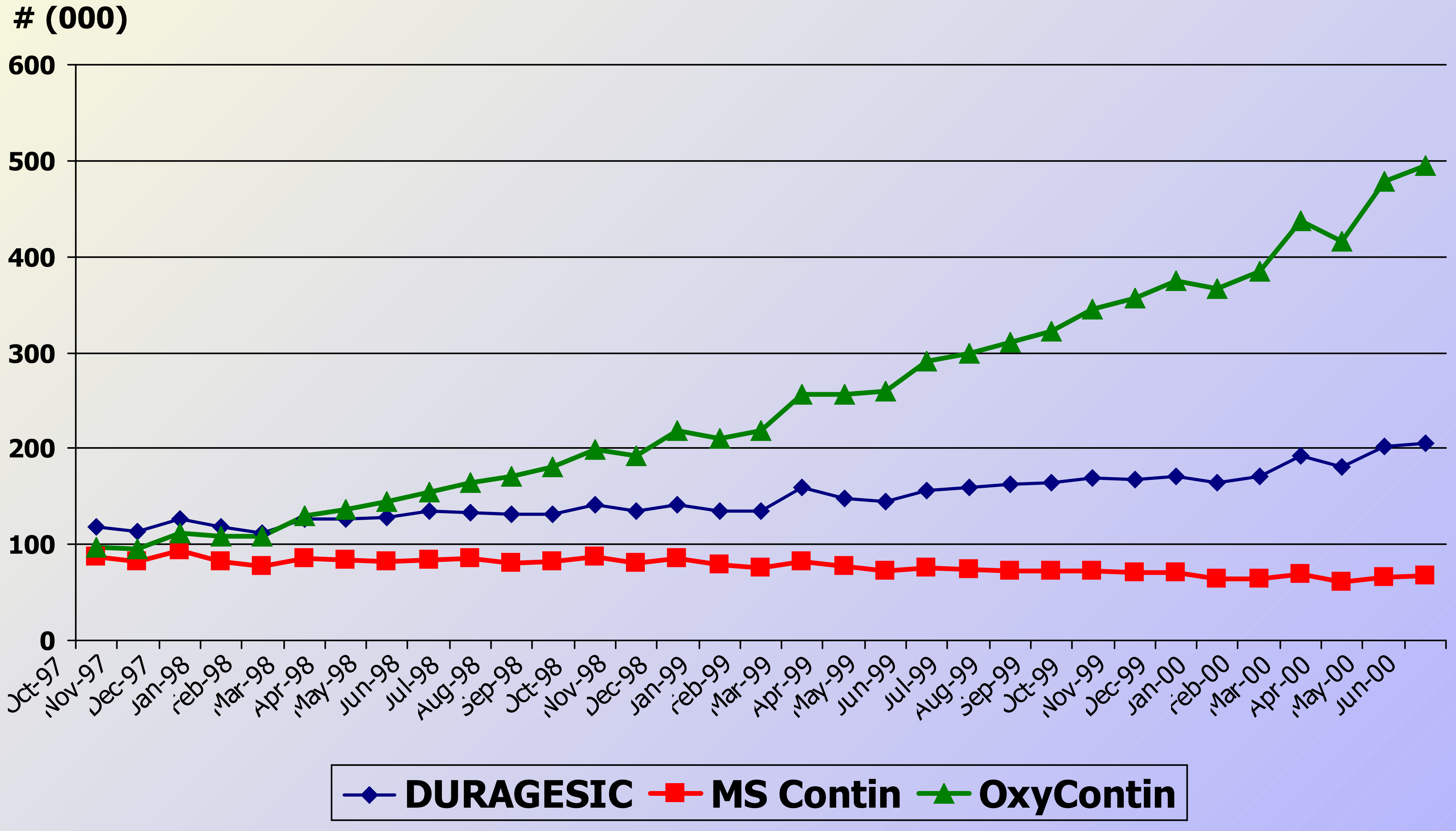
DURAGESIC® Vision

DURAGESIC® will be the first choice

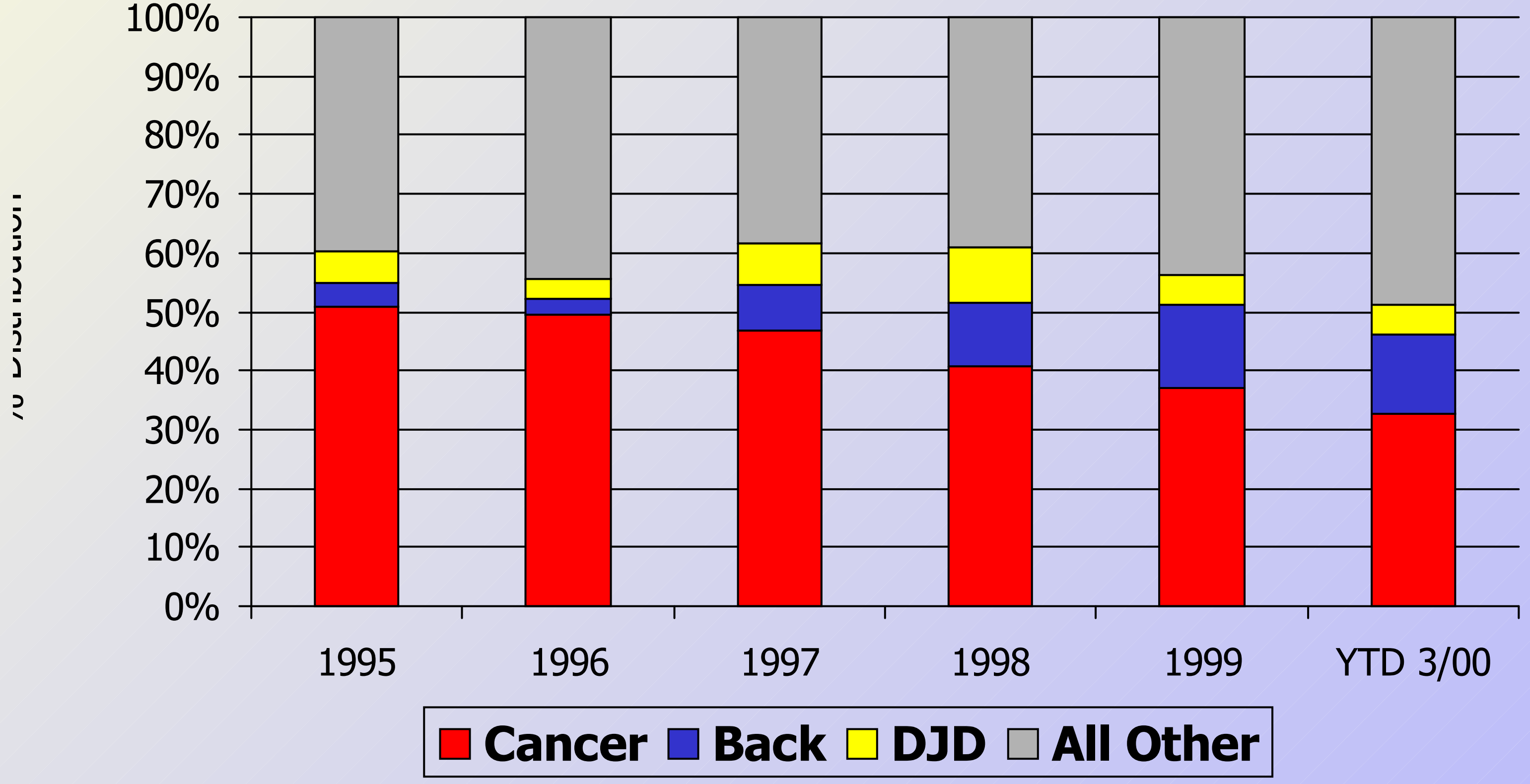
of chronic pain patients

for around-the-clock opioid therapy

LA Opioid TRx Trend



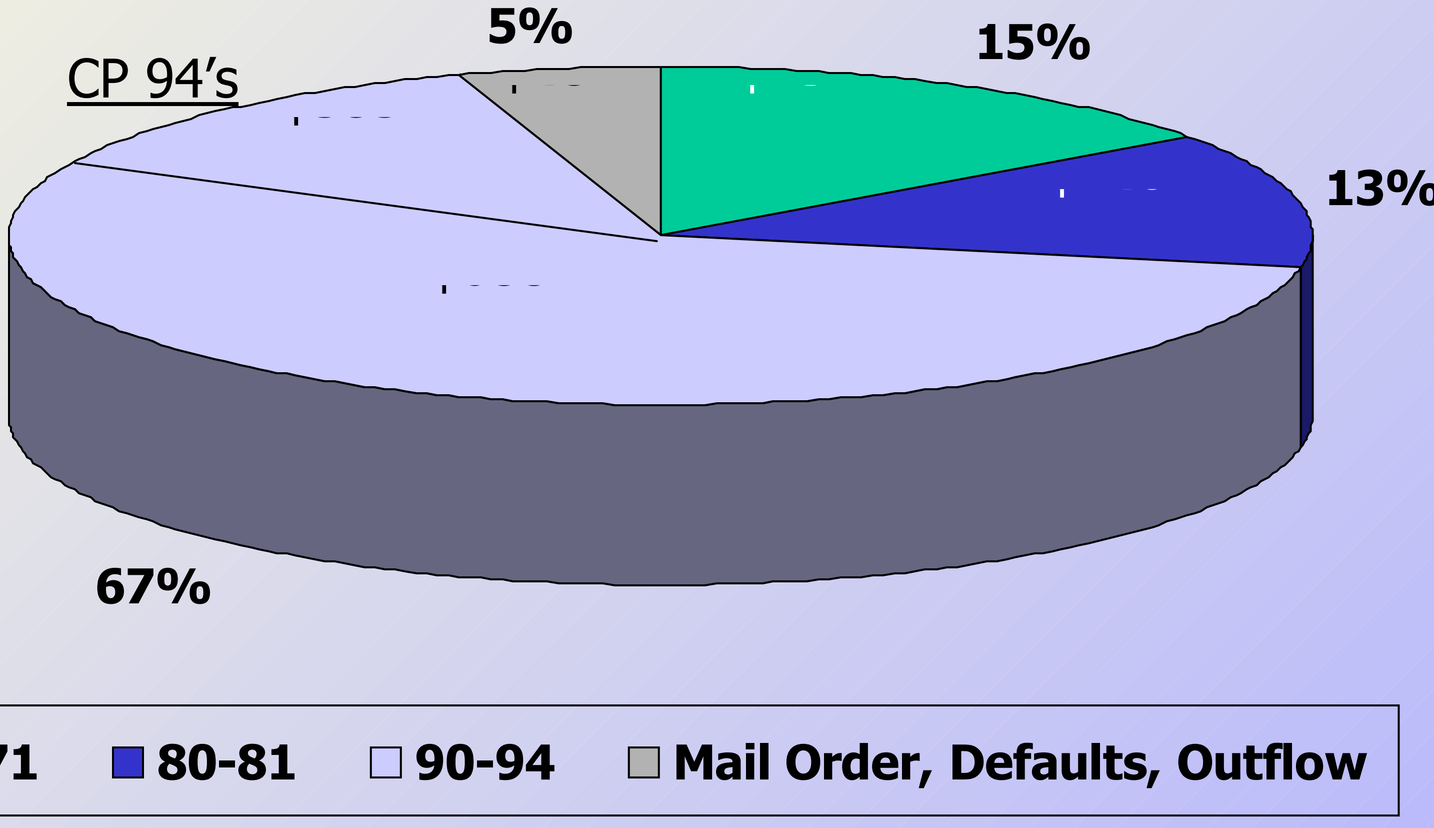
DURAGESIC®
Diagnosis Trends



* Top 3 diags in "all other" include post-op pain, chronic pain syndrome and neuropathic pain

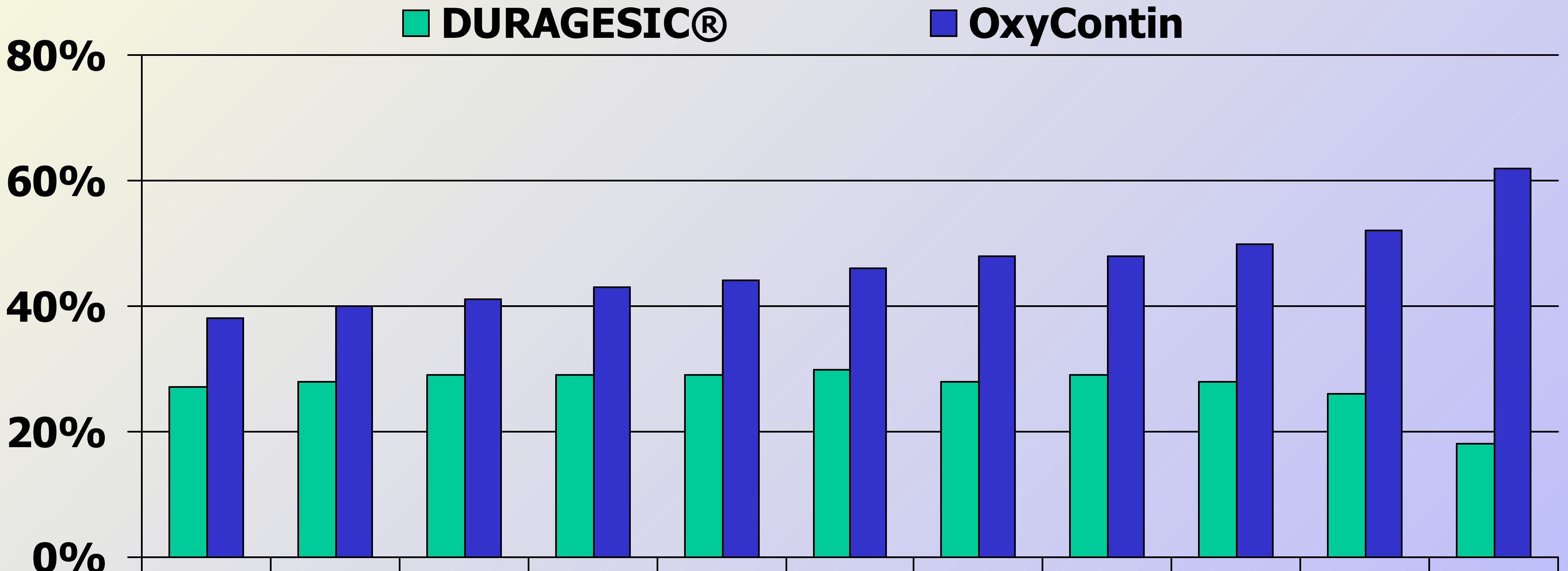
Source: IMS - National Disease and Therapeutic Index (NDTI)

Chronic Pain Xponent Market
All Specialties, Deciles 0-9
$1.03B



April 2000 Deciling

Share of Dollars MAT April 2000



	6.0	6.1	7.0	7.1	8.0	8.1	9.0	9.1	9.2	9.3	9.4
DURAGESIC	27%	28%	29%	29%	29%	30%	28%	29%	28%	26%	18%
OxyContin	38%	40%	41%	43%	44%	46%	48%	48%	50%	52%	62%

DOLLAR DIFFERENCE (MM)

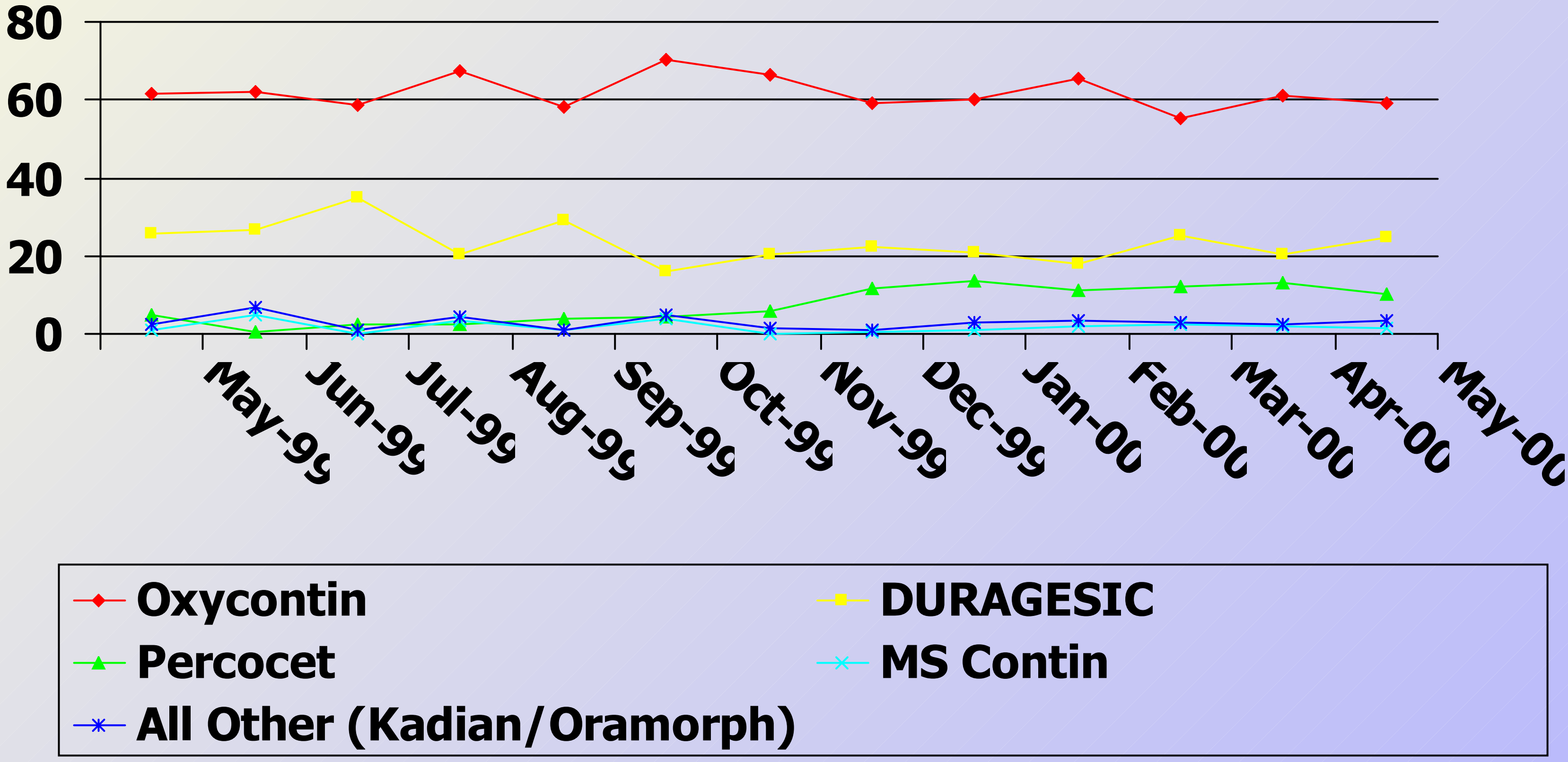
MAT 1/00	1	2	2	3	6	11	7	10	14	27	**143**
MAT 4/00	2	3	4	5	8	14	10	12	18	31	**168**

Janssen versus Purdue Sales Force Alignments

DURAGESIC®		OxyContin	
275 OB (ACX, **DRG**)	275	Purdue * (**OXY**, MSC)	700
HSR (ACX, **DRG**, SPX)	109	Abbott (Anzemet, Ultrane, **OXY**)	109
ElderCare (RIS, **DRG**, ACX)	85		
OrthoBiotech (PRO, **DRG**)	242		

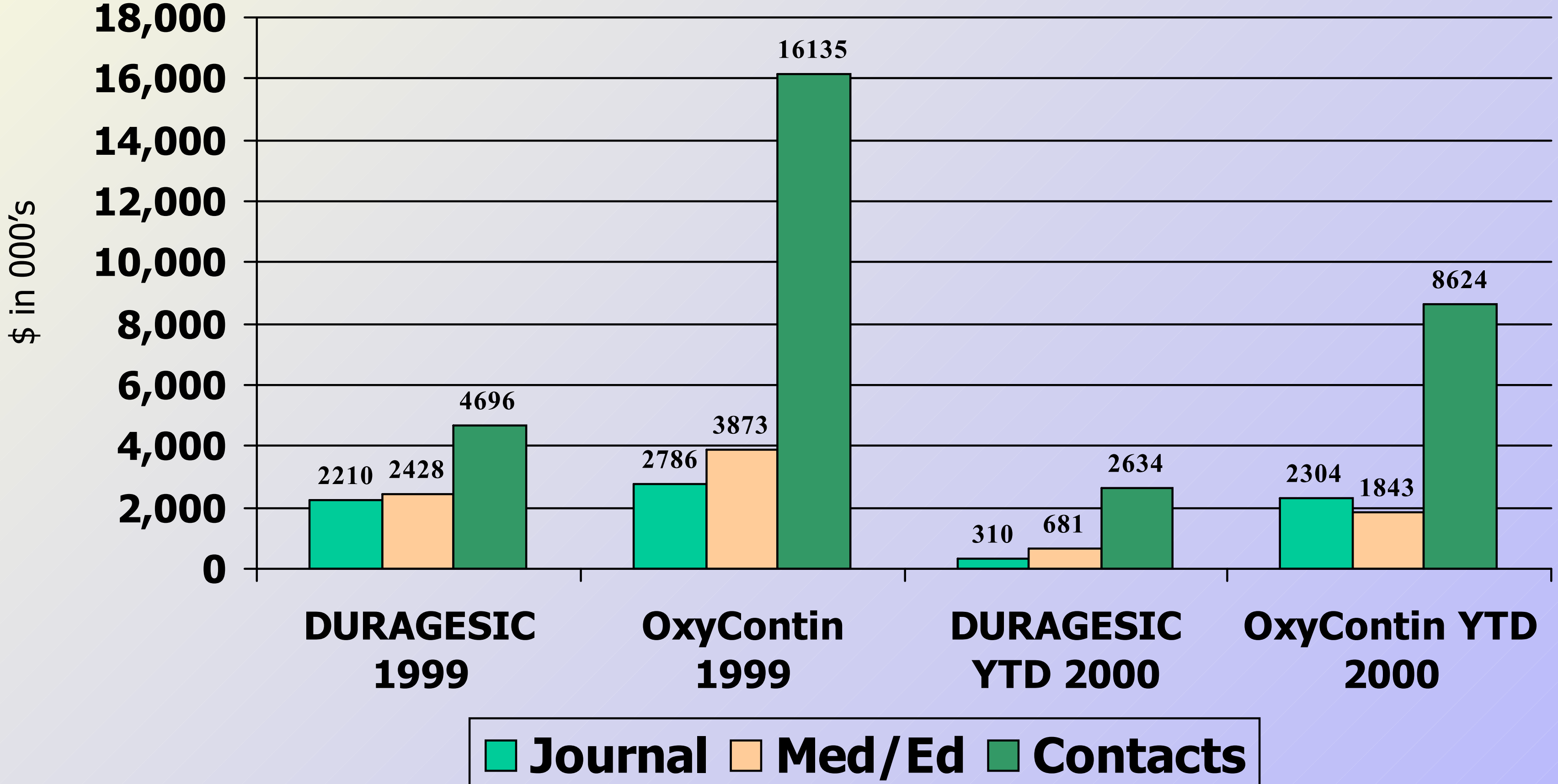
*Purdue currently expanding by 100-150 reps in anticipation of Palladone launch

Chronic Pain Market Share of Contacts



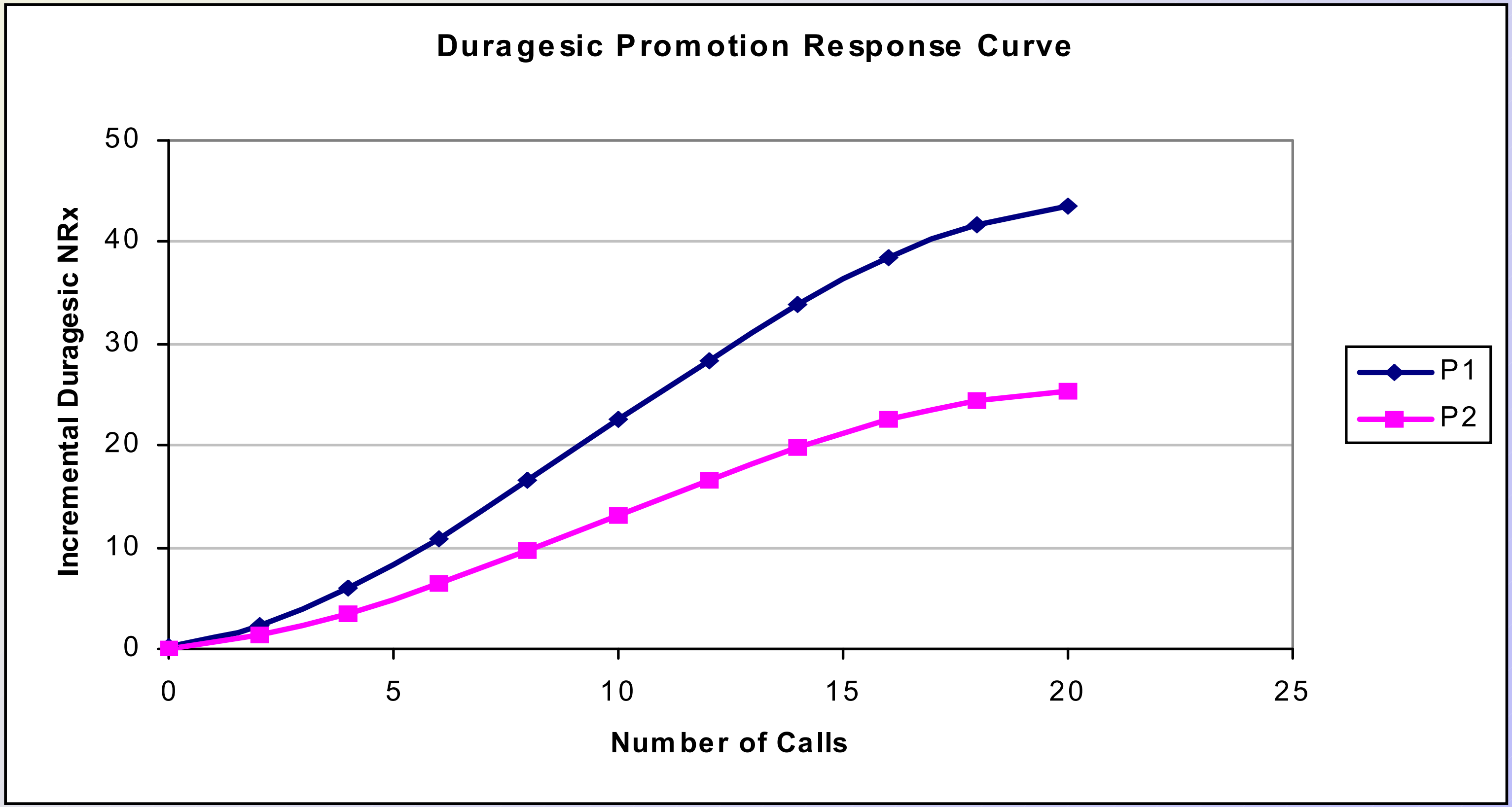
Source: IMS - IPS

DURAGESIC® Versus OxyContin PME Spend/ Contacts



Sources: IMS - Integrated Promotional Services(IPS) & Scott Levin - Physician Meeting & Event Audit (PMEA)

DURAGESIC® Promotion Response Curve Pain Specialists



Analysis based on deciles 6 to 9 pain specialists

* - The data does suggest that for decile 9 pain specialists, frequency levels of 24 or 25 still bring in incremental value

Frequency Versus NRx Change (Decile 9 Physicians)

Previous Quarter Calls	Current Quarter Calls	Previous NRx/ MD	Current NRx/ Mo	NRx Diff (0%)
0	0	11.4	11.3	(1.0)
0	1, 2	10.7	11.2	5.0
0	3, 4	11.1	12.3	10.4
1, 2	0	10.7	10.4	(2.8)
1, 2	1, 2	11.7	11.9	1.8
1, 2	3, 4	11.6	13.3	14.3
3, 4	0	13.0	12.5	(3.7)
3, 4	1, 2	12.7	13.2	4.2
3, 4	3, 4	18.4	21.1	14.5

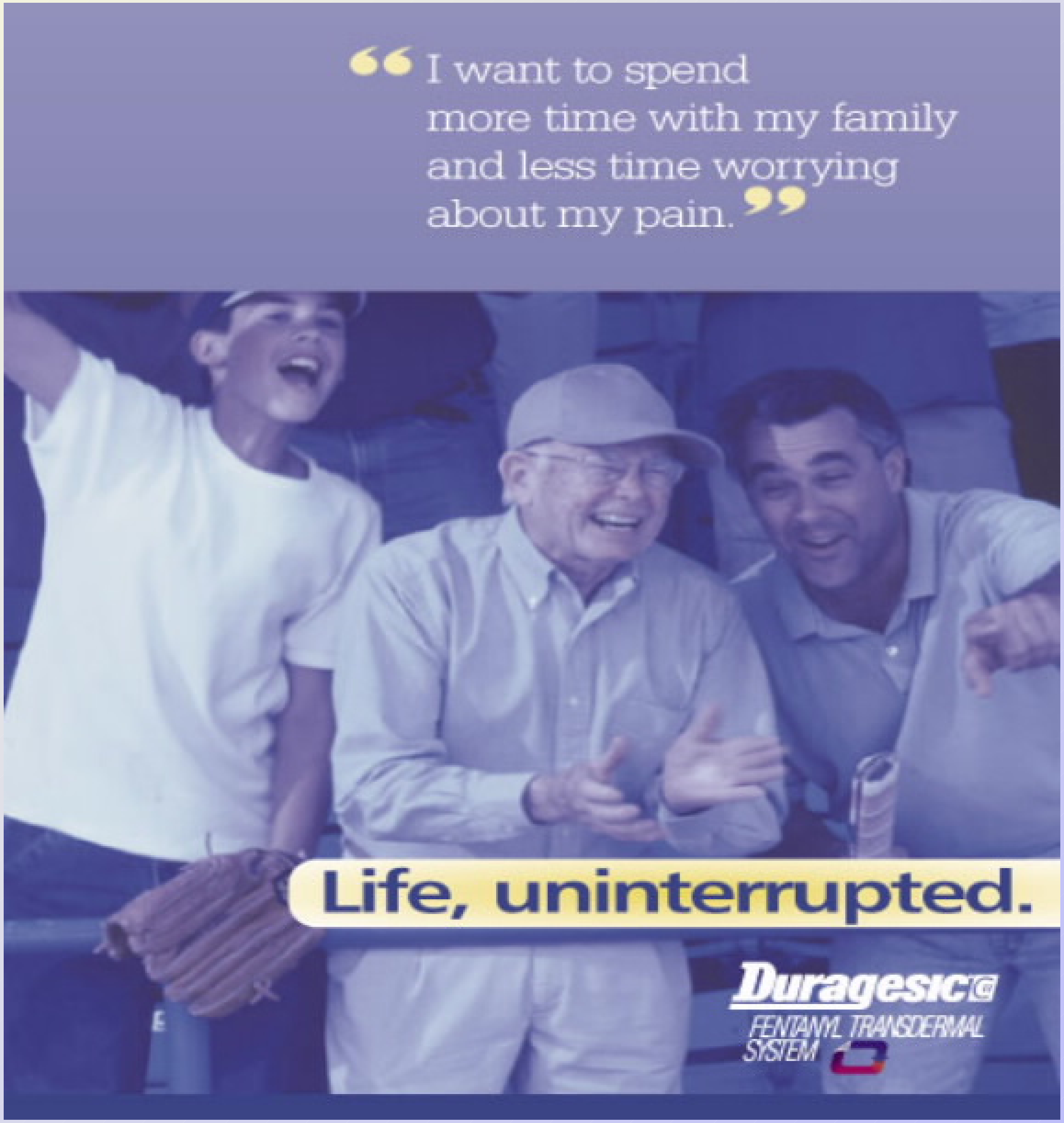
DURAGESIC® Quadrant Analysis: PCP's and Anesthesiologists (non-malignant)

- DURAGESIC's higher scores are on more important attributes:
  - Efficacy
  - Dosing
  - Quality of life and patient outcomes
  - Patient preference and compliance
- DURAGESIC's lower scores are on less important attributes:
  - Safety and side effects
  - Cost
  - Regulatory issues and concerns
- This is an ideal pattern of attribute scores

DURAGESIC® Competitive Advantages

These advantages are the basis of our message!

- Reduces pain the most
- Patient satisfaction with pain relief
- Patients able to regain functionality
- Patients able to enjoy life despite chronic pain
- Overall efficacy in treating chronic pain
- Patients think about their pain less
- Low incidence of constipation (low importance)


"I want to spend more time with my family and less time worrying about my pain."
Life, uninterrupted.
Duragesic
FENTANYL TRANSDERMAL SYSTEM

Key Findings: Reaction to Print Executions

- **Key message:** 3-days continuous pain relief
- **Benefits:**
  - Convenience
  - Thinking less about the pain
  - Freedom
  - Living a normal life
- **Overwhelmingly positive preference for the patch vs. pills**

Lessons Learned

- Key customer segments currently under-developed
  - Decile 9.3 and 9.4
  - Oncology
- DURAGESIC® promotionally responsive
  - Resourcing against highest RX'ers pays off
  - Progress made in reach/frequency, but substantial upside remains due to fragmented selling time
- DURAGESIC is perceived as a superior LA opioid by target physicians
- DTC will work to drive consumers
  - Unmet needs
  - Lack of understanding
  - High degree of dissatisfaction with current therapies
- Need non-malignant pain data (lower back, OA/RA)

SWOT

Strengths

- Patent life - 2004+
- Patch technology
- Low abuse potential
- Only 72 hour product
- Patient preferred
- Perceived as superior product

Weaknesses

- Resources
- Fragmented selling time
- Limited clinical data
- Niched product
- Pipeline
- Perceived to be more expensive

Opportunities

- Overall pain market growing
- Pain still under-treated
- Opioid acceptance for non-malignant pain
- Greater consumer involvement in management of pain
- Line extensions

Threats

- New competitive entries
- Alternative technology
- State medical boards
- Government intervention/ cost control
- Treatment protocol guidelines

DURAGESIC® Key Issues

- Not competitively resourced
- We need more consistent reach and frequency against 9.3/9.4
- Patients/caregivers are unaware of options
- Non-malignant market is the growth opportunity
  - DURAGESIC data is non-existent
- Product development (current putup and line extensions) is essential to maximizing revenue stream
- Established segments (oncology, geriatrics) are vulnerable

2001 Business Objectives

Qualitative

Competitive share of voice in 9.3/9.4's

Drive patients to request DURAGESIC® in DTC offerings

Broad based dissemination of results of FEN US71/72

Submit claim for patient satisfaction

Recapture market leadership in oncology

Initiate 12.5mcg trials

Quantitative

$550 MM

23.9% December NRx

DURAGESIC® Key Strategies

- Competitive S.O.V. with 9.3/9.4 prescribers
- Expand DURAGESIC use in non-malignant pain
- Position DURAGESIC as 1st opioid choice for chronic A.T.C. pain
- Generate awareness and call to action among patients/caregivers
- Protect established segments (oncology, geriatrics)
- Maximize life cycle opportunities

Competitive SOV with 9.3/9.4

Tactics

- Regional Ad Boards
- Coupon Program
- Incentive to increase compensation
- Home Office Visits
- Physician Locator Network
- TVG
- Journal Ads

Expand DURAGESIC® Use in Non-Malignant Pain

Tactics

- Medical Education
  - FEN 71/72 Information Dissemination
  - Direct Mail
  - Dinner Meetings
  - Spin-Offs
    - FEN 71/72
    - Reg Adv Board
    - Symposia
      - APS
      - AAPM

Tactics

- DTC Advertising
- Down-Scheduling
- Website Enhancement
- Physician Initiated Trials
- MCO Budget Impact Model

Position DURAGESIC® as 1st Opioid Choice for Chronic A.T.C. Pain

Tactics

- Physician Locator
- Targeting Around-The-Clock Opioid Use
- Coupon Programs
- DTC Advertising
- Regional Ad Boards

Tactics

- Home Office Visits
- Speaker Programs
- 12.5 Clinical Trials
- MCO Budget Impact Model

Generate Awareness and Call To Action Among Patients/Caregivers

Tactics

- DTC Advertising
  - DTP in Office/Pharmacy
  - Website Enhancement
  - Physician Locator
  - Loyalty Program
- Patient Education Pieces
- Pharmacy Center (Health Resources)

Protect Established Segments (Oncology, Geriatrics)

Tactics

- Dual Coverage of Office-based Oncologists
- Appropriate Compensation Studies in ElderCare/OBI
- Home Office Visits
- Palladone/ Dilaudid SR Blocking Strategy
- TVG for 9.3/9.4
- Coupon Program for 9.3/9.4

Maximize Life Cycle Opportunities

Tactics

- Down-Scheduling
- Patent Protection
- Matrix Development
- Pediatric Extension
- 12.5mcg/hr strength

Medical Development Clinical Trials

- Active trials
  - FEN-71: DURAGESIC® vs. OxyContin in chronic non-malignant pain
    - 1° endpoint: patient preference
    - Top-line results 1Q01
  - FEN-72: DURAGESIC vs. Percocet in chronic low back pain
    - 1° endpoint: patient preference
    - Top-line results 2Q01

Medical Development
12.5 Clinical Trials

- Osteoarthritis (vs. a short-acting opioid)
  - Strategic objective: position DURAGESIC® as first-line opioid for chronic pain requiring opioid analgesics
  - Efficacy (global treatment assessment); AE profile; Outcomes measures (satisfaction, QoL)
  - Timing
    - Initiate 2Q01 (pending data from FEN-71)
    - Complete analysis 4Q02; report 1Q03

Medical Development
12.5 Clinical Trials

- Low back pain, vs. OxyContin
  - Strategic objective: position DURAGESIC® as preferred long-acting opioid for chronic low back pain
  - Efficacy (preference); AE profile; Outcomes measures
  - Timing
    - Initiate 1Q01
    - Complete analysis 2Q02; report 3Q02

Medical Development
12.5 Clinical Trials

- 25 vs. 12.5μg/hr patch, non-malignant pain
  - Strategic objective: establish 12.5 μg/hr patch as first-line long-acting opioid
  - Compare rates of discontinuation for AE, overall AE profile
  - Study design: Randomization to 25 or 12.5 μg/hr patch
  - Timing
    - Initiate 4Q01 (At time of NDA submission)
    - Complete analysis 1Q03; report 2Q03

Medical Development
12.5 Clinical Trials

Study (sample size)	Total study costs ($M)	2001 ($M)	2002+ ($M)
Osteoarthritis (244)	$3.8 – 4	$1.4	$2.5
Low back pain (244)	$3.4 – 3.5	$1.5	$1.9
25 vs. 12.5 μg/hr (800)	$4.4	$0.6	$3.8
Total		$3.50	$8.20

Medical Services

- Expand DURAGESIC® use in chronic non-malignant pain
  - Chronic pain guideline presentations
  - Chronic pain CME/ACPE; 2Q01 - $10,000
  - Clinical presentation -- managed care/LTC accounts -- stress patient satisfaction, caregiver implications
- Maximize life cycle opportunities
  - Hospice/Eldercare presentation 2Q01
  - DURAGESIC *Medication Use Evaluation* 3Q01

Medical Services

- DTC generate awareness
  - Regional Pharm.D. to meet proactively with key customers -- alert them of DTC campaign -- review purpose and strategy 4Q00/1Q01

2001 Analgesia Outcomes Research Plan

Scope of the Problem:

- Lack of data in chronic non-malignant pain
- OxyContin has extensive data in non-malignant pain
  - – Label claim for improved QoL, sleep, and mood
- (Mis)perception that DURAGESIC® is more expensive than OxyContin
- Propoxyphene dominates nursing homes

Outcomes Research Must Address Issues of Key Customer Segments

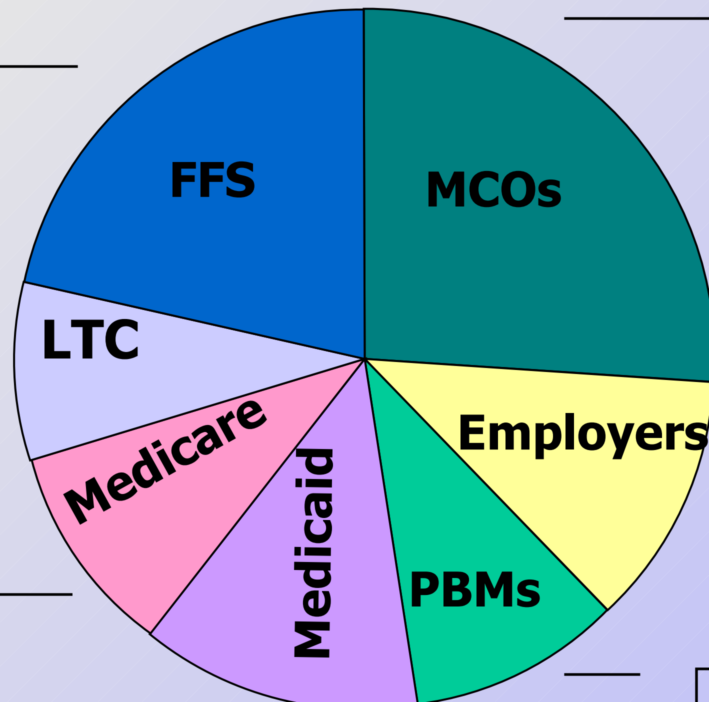
Pharmacy Director:

Costs

- Satisfaction
- Functionality
- Costs

Medical Director:

- QoL
- Satisfaction
- Functionality



- Costs in nursing home and hospice
- Undertreatment of chronic pain

- Functionality
- Missed work days

Costs

Costs

Costs

Relevant Outcomes to the Chronic Pain Market

Satisfaction

- treatment
- home
- work

Quality of Life

- social
- recreational
- sleep

Functioning

- physical
- mental

Pain Symptoms

“Satisfaction” as an Outcome

DURAGESIC® Effectiveness Trial

<u>Objective</u>: Obtain a DDMAC claim for DURAGESIC demonstrating better satisfaction over OxyContin

<u>Secondary</u>: Pain interference on activities of daily living (QoL)

Timing: Preliminary Results - November 2001

Patients Able to Regain Functionality

Worker's Compensation Study

<u>Objective</u>: Demonstrate that DURAGESIC® patients are able to return to work sooner than patients on other long-acting opioids

Timing: Preliminary results -- July 2001

Quality of Life Data at University of Utah

<u>Objective</u>: Show a significant increase in physical functioning in patients taking DURAGESIC

Timing: Preliminary results -- May 2001

Linking Key Business Plan Issues and Messages to Outcomes Research in 2001

Patient Satisfaction with Pain Relief

- DURAGESIC® Effectiveness Trial ($800,000)
- Satisfaction Survey in MCOs
- Satisfaction Survey in LTC (assisted living)
- FEN-71/72 subanalyses
- 12.5 mcg outcomes component to Phase IIIb studies

Patients Able to Enjoy Life

- Depression-Pain study

Patients Able to Regain Functionality

- Disability/Worker's Compensation study
- University of Utah/TOPS retrospective study

Addressing the Misperception that DURAGESIC is More Expensive than OxyContin

- Cost-Utility Model
- DURAGESIC Cost Calculator
- Replicate Medi-Cal study in other Medicaid states and MCOs
- Fecal Impaction study

Increase Opioid Acceptance for Non-malignant Pain

- Aberrant Drug-Taking Behavior Checklist

Address Undertreatment of Pain

- Use of validated FLACC in hospice customers

Budget: $1,782,500

Market Research

Program	Objectives	Timing
Competitive Assessment: OxyContin & Palladone	Monitor competitive detail activity, message delivery, and usage	1Q 01 (Palladone) 1Q, 3Q 01 (Oxy)
Usage & Awareness and Tracking Survey with Perceptual Mapping	Ongoing tracking of market knowledge, attitudes, and practices of short- and long-acting opioids in chronic pain	4Q 01
Post-Launch Usage & Awareness Survey for DTC Print Ads	Quarterly post-launch tracking of attitudes and practices	1Q – 4Q 01
Post-Launch Qualitative MD Assessment of Patient Rxn to DTC Print Ads and Professional Programs	Potential refinement of DTC promotional programs and print ads; identification of gaps	2Q 01
Development of 2nd DTC Print Ads	Qualitative and quantitative tip-in studies: qualified, nonqualified, and caregivers	3Q – 4Q 01
Internet Unmet Needs and Usage: Patients and Physicians	Assess patient and physician usage and needs on the internet for chronic pain management	2Q 01

Continued...

Market Research

Program	Objectives	Timing
Focus Groups with Targeted Physician Specialities: Positioning and Message Effectiveness	Assess effectiveness of positioning strategy and identify gaps in promotional message among PCPs and specialists	2Q 01
12.5 Opportunity Assessment – Positioning Strategy	Identify optimal global positioning strategy of 12.5ug DURAGESIC patch through quant study	2 – 3Q 01
Hospice and Long-Term Care Opportunity Assessment	Assess needs of hospice segment and long-term care and perceptions and usage of DURAGESIC	2 – 3Q 01
Multilaminate Opportunity Assessment	Assess potential business opportunity of multilaminate patch	1 – 2Q 01
Oncology Focus Groups	Reassess DURAGESIC usage and perceptions in treating malignant pain and assess usage of Palladone	2Q 01
Rep/Doc Study – DURAGESIC®	Assess detail activity and message delivery by Janssen/OBI/Eldercare	2Q 01
Best Practices Survey	Evaluate rep efficiency in details and message delivery	2Q 01
Convention Research - Surveys	Assumes four separate surveys	1 – 4Q 01

Business Imperatives

- Resources need to be invested and targeted to match OxyContin S.O.V. among high prescribers
- Define treatment options for non-malignant pain
- Successful execution of DTC initiative
- Protect DURAGESIC® business in established segments (oncology, geriatrics)
- Data available at launch of 12.5
- Launch mentality

DURAGESIC®
2001 Business Plan

Forecast &
PME Requirements

DURAGESIC®: 2001 Business Plan Forecast

DOWNSIDE

$485 MM

ASSUMPTIONS:

- No DURAGESIC DTC Advertising
- PF Launches DTC
- Continued S.O.V. Deficit
- No Primary Calls
- Oncology Share Loss to Palladone

BASE CASE

$550 MM

ASSUMPTIONS:

- DTC Q1
- 275 SF Primary
- 500 SF Secondary
- Market Maintain 30% Growth Rate
- Share Stable in Oncology

UPSIDE

$633 MM

ASSUMPTIONS:

- Competitive SOV
- DTC Drives Market Growth Acceleration
- Successful Blocking of Palladone Launch
- Oncology Share Growth

DURAGESIC®

2001 Business Plan Forecast Assumptions

% TRx Share - (Avg. Annual Share)

	1999	2000 YTD	2000*	2001*
DURAGESIC	23.4%	21.3%	21.0%	22.5%
MORPHINE SULFATE	2.5%	3.3%	3.2%	3.4%
MS-CONTIN	11.2%	7.6%	6.4%	4.1%
OXYCONTIN	43.8%	48.6%	48.9%	50.5%
PERCOCET	15.9%	16.3%	17.9%	17.0%
TOTAL OTHERS	3.2%	2.9%	2.6%	2.5%

**Projected*

DURAGESIC® PME Requirement

Overall PME requirement = $62 MM

	1998	1999	2000	2001*	2002*
Net Trade Sales (MM)	244.6	324.7	400	550	691.3
PME Requirement	14.6	24.8	32.4	62	70.0
% of Net Trade Sales	6%	8%	8%	11%	10%

*Projected

DURAGESIC® Allocations

OTHER

Med

-Symposia

-TVG

-Dinner Meetings

-Experts Meetings

-Publication/ Promotion

DTC

-Media

-Agency

-P.R.

-Fulfillment

-Call Center

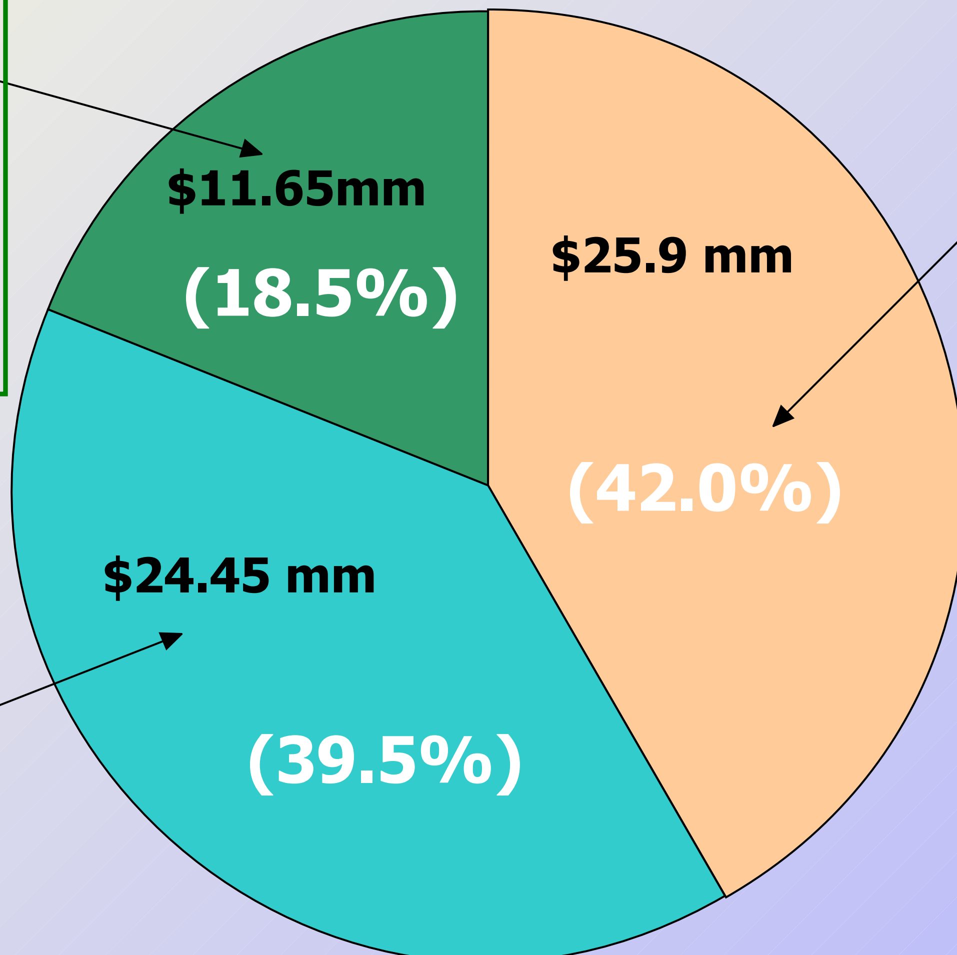
SALES FORCE(S)

-775 OB

-107 HSR

-185 EC

-285 OBI



DURAGESIC® PME 2000 vs 2001 by Major Line Item

Description	PME ($K)	PME (%)	PME ($K)	PME (%)
Journal Advertising	1,321	4%	2,250	4%
Non-Media Advertising	458	1%	500	1%
Agency Fees	1,585	5%	3,200	5%
Sales Training/Incentives	4,075	13%	2,000	3%
Sales Aids/Promotion	3,832	12%	6,200	10%
Medical Education	9,062	28%	13,650	22%
National/Scientific Exhibits	330	1%	500	1%
Public Relations	709	2%	1,500	2%
DTP/DTC	6,000	19%	23,200	37%
Regional	3,865	12%	6,300	10%
Other	1,155	4%	2,700	4%
TOTAL PMEs	$32,392	100%	$62,000	100%

Field Support Budgets

Field Team	FTEs*	Grants ($)	Entertainment ($)	Access
• 275 OB	141	.45	.825	.990
• HSR	38		.428	.385
• 500 Gold	110	.32	1.000	1.200
• ElderCare	25		.185	.333
• SAM/ SADS/ KAISER	-		.040	.096
TOTAL	314	.77	$2.478	$3.004

*** Based on percentage of presentations**

DURAGESIC® Key Events Map

Short Term	Intermediate Term	Long Term
6 - 12 Months	9 - 24 Months	18 + Months to Patent Expiration
Targeting	DTC	12.5
Frequency	Clinical Trials	Matrix
Calls	- 71	Patent Extension
Message	- 72	
Education (Rep)	- Outcomes	
Education (Phys)	- EMRP	
	- Phase IIIB - 12.5mcg	

Oncology/Geriatrics
- Coverage
- Palladone

Down-Scheduling

L & A

Summary

- Foundation for success is in place
- DURAGESIC® must “Resource our Resources”
- DTC offers significant upside potential
- Marketing, Sales, and Clinical are aligned around priorities and objectives
- Launch Mentality